

## **REMARKS**

Claims 1, 11, 26 and 27 now recite a proper claim status identifier.

Claims 21 and 28 are now recite the correct claim status identifier.

The objection to claim 12 is not understood since it was correctly presented in the Response After Final that accompanied the Request for Continued Examination. According to the undersigned's file copy, the newly added material was underlined the misspelling of an original claim term was corrected. Thus, it is not clear what needs to be done.

Claims 1, 11-12, 16-18 and 26-28 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11,12,16-18 and 26-28 of copending Application No. 11/624,777.

Claim 1 of copending Application No. 11/624,777 was retained for purposes of continuity and will be cancelled in due course. Claims 1, 11-12, 16-18 and 26-28 of copending Application No. 11/624,777 were cancelled in the Preliminary Amendment filed on January 19,2007.

After claim 1 is cancelled, claims 140-157 will be pending. Claim 140 of copending Application No. 11/624,777 concerns a transgenic oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 2.0% of **arachidonic** acid. This acid has twenty carbon atoms and only **four** double bonds. In contrast, claim 1 of the instant application recites a transgenic oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 1.0% of at least one polyunsaturated fatty acid having at least twenty carbon atoms and **five or more** carbon-carbon double bonds. Accordingly, it is respectfully submitted that the claims are patentably distinct. It is respectfully submitted that the claims are not co-extensive since they differ in the number of double bonds that are present.

Accordingly, withdrawal of the provisional obviousness-type double patenting rejection is respectfully requested in view of the above-discussion.

Claims 1, 11-12, 6-18 and 26-28 remain rejected under 35 USC §112, first paragraph, on the ground that enablement is not provided "for claims broadly drawn to any oilseed plant containing any transgene and producing oil exhibiting any fatty acid profile." It is stated on page 5 of the Office Action that the "Kinney declaration of

23 March 2007 is not persuasive because it remains unclear whether the references cited utilized the techniques and constructs taught in the specification. . . .”

It should be noted at the outset that the pioneering work which constitutes the subject matter of this invention concerns placing a marine DHA and/or EPA biosynthetic pathway into oilseed plant and recovering significant amounts of DHA and/or EPA in the seed oil. **This was not known prior to Applicants’ disclosure.**

Assuming *arguendo*, that it was possible to recreate these marine pathways in the seeds of land-based plants, it was not known what the endogenous “machinery” of a land-based plant would do with these pathways. It was not known if a resulting LCPUFA would be incorporated into the seed oil. Bear in mind that the endogenous machinery of land-based plants had **never** dealt with such fatty acids before, thus it was not clear to one of ordinary skill in the art as to what the outcome would be.

The outcome was unknown until Applicants demonstrated for the very first time in one oilseed plant. This is what is set forth in the above-identified application. Once this had been demonstrated, it can then be used in any oilseed plant that has comparable endogenous machinery. In other words, demonstration in one land-based oilseed plant that its endogenous “machinery” was capable of using the LCPUFAs to make DHA and/or EPA is a demonstration with respect to any oilseed plant that has the same machinery, i.e., all oilseeds.

This is demonstrated quite clearly in the instant specification wherein an EPA pathway was added to another oilseed plant, Arabidopsis, and observing the resultant EPA appearing in the oil of the seed. Further support can be found in the research of Dr. Wu (discussed below) who added an EPA pathway to Brassica using the method disclosed in the specification. The fact that the level of expression in Brassica was not the same as in soybean or Arabidopsis is irrelevant since the level of expression achieved certainly fell within the parameters recited in Claim 1 :

a transgenic oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises **at least 1.0 %** of at least one polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds.

The Kinney Declaration discussed the Robert article which was discussed at the February 13, 2007 interview. Attention was kindly invited to Table 1 on page 105 of the Robert article. This table summarizes genes, host plants and reported LC-PUFA proportions in seeds of transgenic plants:

Column 1 references the work of Abbadi et al. (2004) with respect to flax.

Column 2 references the work of Kinney et al. (2004) (which constitutes the subject matter of the instant application.)with respect to soy.

Column 3 references the author's work in 2005 with respect to *Arabidopsis*; and

Column 4 reference the work of Wu et al. (2004 with respect to *Brassica*/rapeseed.

The Robert article then goes on to discuss Dr. Kinney's work in column 1 on page 106 (and also mentions the instant patent application and publication). The work of Wu et al. is discussed in column 1, second paragraph. The Robert article states that **Dr. Wu used Dr. Kinney's method to produce high levels of AA and EPA in rapeseed**. Specifically, a delta-17 desaturase was used to shunt a large amount of AA into the n-3 pathway at EPA. **Thus, Dr. Wu's work demonstrates that Dr. Kinney's method worked with respect to *Brassica***. Irregardless of the LCPUFA oil level, Dr. Wu did exemplify the use of Dr. Kinney's method to achieve expression of LCPUFAs in *Brassica*, **a different oilseed plant than soy**. LCPUFAs were recovered. This further shows that the specification is indeed enabling.

Furthermore, it is noted that a number of different EPA/DHA genes from different sources are presented in the specification to produce EPA/DHA oils in transgenic oilseeds. It should be clear from the specification that as long as a pathway is capable of producing DHA and/or EPA, then that pathway can be used to produce such fatty acids in seed oils.

Attention is kindly invited to Figure 1 of Damude (2007) (previously submitted). This figure depicts aerobic LCPUFA biosynthetic pathways in marine microbes. In other words, there are a number of pathways available that could lead to the same product. Attention is kindly invited to Damude et al. (2007) second column on the third page through column 2 on the fifth page. This section discusses a variety of

fatty acid biosynthetic pathways that can be considered in engineering omega-3 LCPUFAs in plants (also depicted in Figure 1).

Thus, Dr. Kinney's declaration also was intended to demonstrate that a variety of genes (from different sources) and combinations thereof can be used to engineer production of omega-3 fatty acids in oilseed crops. The art cited by Applicant demonstrates that, contrary to the last sentence on page 5 of the Office Action, the instant invention is not limited to any particular combination of enzymes (and genes encoding them). The choice of genes will vary depending on which pathway is chosen, for example, whether a delta-6 or delta-8 pathway is chosen to engineer expression of an LCPUFA in a oilseed plant. The Napier, Wu and Damude articles all support this point.

Claims 1, 11-12, 16-18 and 26-28 stand rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement.

The above discussion is believed to be apposite to this ground of rejection as well.

Parenthetically, a reference was made to DPA in the second full paragraph on page 6 of the Office Action. Attention is kindly invited to Table 8 on pages 64-65 of the specification which sets forth an analysis of transgenic somatic soy embryos and seed chips containing EPA and DPA. Other data is presented elsewhere in the examples.

Accordingly, withdrawal of the rejections of claims 1, 11, 12, 16-18 and 26-28 under 35 USC §112, first paragraph, is respectfully requested.

It is respectfully submitted that the claims are in form for allowance which allowance is respectfully solicited.

A Petition for a two (2) month Extension of Time accompanies this Response.

Please charge any fees or credit any overpayment of fees which are required in connection with the filing of this Response After Final to Deposit Account No.

04-1928 (E. I. du Pont de Nemours and Company).

Respectfully submitted,

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